MAR 0 6 2003

K022855

Bio-Medical Research Ltd
Parkmore Business Park, West
Galway
Ireland

510 (k) Summary of Safety and Effectiveness.

This summary is submitted in accordance with 21 CFR 807.92

a)	1	Submitted by	Bio-Medical Research Ltd BMR House Parkmore Business Park, West Galway Republic of Ireland
		Establishment Registration Number	8020867
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		Title	Regulatory Affairs Manager
		Date of Preparation	August 2002.
	2	Trade Name of Device	Slendertone FLEX Bottom & Thigh Toning system. Type 511.
		Common Name	Muscle Stimulator
		Classification name	Powered Muscle Stimulator
	3	Identification of predicate device	Slendertone FLEX Abdominal training system. K010335

FDA/CDRH/ODE/DMC
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4 Description of Device

Slendertone Flex Bottom and thigh toning system is a two- channel battery operated muscle stimulation system specifically designed to exercise the bottom and thigh muscles. It comprises two main components, namely, an electronic stimulator module which generates the required stimulation signals, and a shorts garment with integral electrodes, which connects the signals from the stimulator to the skin. The electrodes are located on the inner surface of the shorts. In effect, the shorts in this case take the place of the lead wires commonly found in most conventional muscle stimulators.

The product is supplied with a set of double- sided adhesive electrodes, an instruction manual, a set of batteries, and a carry pouch. Power is derived from three LRO3 cells located in a compartment protected by a removable battery cover.

Although a two- channel system, there are six electrodes. The electrodes connect adhesively to studs on the inner surface of the shorts. The garment is worn as shorts, with the leg openings and waist secured by Velcro fastening patches. When the shorts are on the body two electrodes (1each side) are located over the gluteal muscles, placed horizontally in the midline of the buttock and the larger two (one at the back of each leg) over the hamstring muscles. Two electrodes are located on either side of the top of the front of the thighs following the linguinal line to act on the quadriceps muscles.

There is no current passed from side to side. Because the user has no access to the wiring or connectors within the shorts, he/she cannot alter the current path and so the possibilities for mis-use are greatly reduced.

5 Intended Use

The Slendertone Flex Bottom and thigh toning device is intended for use by healthy persons to apply trans-cutaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes;

- Improvement of muscle tone to the bottom and thighs.
- Strengthening of the muscles in the bottom and thighs, specifically the quadriceps and hamstrings.
- Improvement to firmness in the bottom and thighs.

6 Technological Comparison

The Slendertone FLEX Bottom and Thigh Toning System is the same as the Slendertone FLEX Abdominal training system in it's delivery of the stimulation signal and has similar parameter setting. There are similar restrictions between the two devices in that electrode positioning is governed by and integral to the garment. Both products utilise a LCD screen with user compliance logging.

Non clinical Tests

Comparisons of electrical outputs for the two devices show similar results. They have both been designed and independently tested to the following requirements;

- IEC 60601-1:1990 Medical electrical equipment – Part 1: General requirements for safety.
- IEC 60601-2-10
- IEC 601-1-1 and appendices A1:1991,A2:1995
  IEC 601-1-2: EMC requirements
- IEC 61000-4-2:1995: Electromagnetic compatibility
- IEC 61000-4-3:1997: Electromagnetic compatibility
- DD ENV 50204:1996: Electromagnetic compatibility
- EN 55011:1998: radiated emissions.

Bio-Medical Research Ltd, (BMR), adheres to recognised and established industry practice, and all devices are subject to final performance testing.

A hazard analysis, a risk analysis and a failure mode effects analysis have been carried out for the device.

2 Controlled study.

BMR conducted a prospective, controlled, single blind, stratified, randomised study with 60 female volunteers to measure the effects of a program of EMS on the bottom and thigh muscles over an eight week period, using the electrode positions and stimulation parameters of the Slendertone FLEX Bottom & Thigh Toning system. The study was designed and carried out by BMR at its consumer research centre in Galway, Ireland.

In psychometric tests, the treated group in the study reported a marked improvement in firmness compared to the control group over the period of the study. Moreover, the treated group showed improvements in self-image and well - being. The control group did not report such an improvement.

In objective measurements of isokinetic and isometric muscle strength, the treated group showed average increases in muscle strength of 11% (extension torque at 15 ˚ and 38.1% (Flexion torque at 15˚), this improvement continued throughout the study duration.

While marginal improvements shown by the control group were initially observed, this was rationalised as being the result of learning effect and improvement had stabilised by week 4 of the study.
When the Full 8 week study had been completed very large differences were observed between the treatment and control groups in terms of muscle strength.

Weight changes were controlled and pre and post measurements indicated that the treatment group did not change in weight .

3 Test Conclusions

Testing of the stimulation output parameters of the Slendertone Flex Bottom & Thigh toning device indicates that it is safe, and that it provides appropriate stimulation output for the bottom & thigh muscle groups. The controlled study indicates that users experience a significant improvement in muscle tone, strength and muscle firmness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

Michelle Sawyer
Regulatory Affairs Manager
Bio-Medical Research Limited
BMR House
Parkmore Business Park, West
Galway
Republic of Ireland

Re: K022855
Trade/Device Name: FLEX Bottom and Thigh Toning System, Type 511
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 3, 2002
Received: December 6, 2002

Dear Ms. Sawyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K022855

Device Name: Slendertone Flex Bottom & Thigh Toning System, type 511-01

Sponsor Name: Bio-Medical Research Ltd.

The device is intended for over the counter sale.

Indications for Use:

- Strengthening, toning and firming of the bottom and thigh region.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use

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(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022855